Questions & Answers

Analysis of Samples, RFQ-RT-03-00081

1) What are the desired quantitation limits that EPA wants to achieve for samples analyzed under this study?

0.1 - 300 microgram / mL of blood, brain homogenate, or biological buffer solution

2) What are the actual qualifications for analytical technicians that are requested under Attachment B Item i-4 and where can the text of the clinical Laboratory Improvement Act of 1988 be accessed?

We have determined that this requirement was not necessary and can be deleted.

3) What certifications or licenses are actually required under Attachment B item i-9?

No specific licenses and certifications, as they vary by state. Identify the licenses and certifications that the firm operates under.

4) When does the EPA anticipate that the analytical work will actually begin for this project? For instance will it be within the next 30 days, 2-months, 6-months, etc?

Within 2 months after awarding the contract.

5) Has the exposure portion of the study already begun? If not, what is the anticipated start date for it?

Exposures have occurred and more are scheduled intermittently during the next 3 years.

6) Who is conducting the exposure study with the test animals? Is it the EPA or is it another contractor? If another contractor, what is the name of the firm?

The EPA is conducting the exposure studies in its laboratories in RTP, NC.

7) Are there actual funds available for the work described in this RFQ?

Yes.

8) We will need at least 20-50 mL of blank matrix material to spike standard curves and prepare QC samples. Will this Material Be provided by the Project Officer?

The EPA will supply the blank matrix material along with samples of unknown concentration for analysis. It would be helpful for the bidder to specify how much of each matrix material will be required so that we can provide sufficient quantities at the time of shipment.

9) Are there any specific storage requirement for the samples after they have been analyzed? Will any remaining samples (if any) be returned to the Project Officer upon completion of testing?

EPA have no need to store the tissues samples after they have been assayed and the results reviewed for consistency with standard curves and experimental conditions. Thus they may be disposed of at the time the EPA accepts the service.

10) Could you tell me if the methods to used are validated or compendial methods? If so, where are they Located?

The EPA maintains a website with standardized methods for chemical analyses at http://www.epa.gov/ttn/amtic/. The compounds that are listed in the RFQ are Air Toxics, subclassified in the compendial document at that site as VOCs (volatile organic compounds). The methods there appear to be specific for detection of low concentrations of these compounds from airborne mixtures, and may not therefore be very useful for the purposes of the present RFQ. This is because it appears to me that these methods involve isolation of a particular compound from a mixture of other similar compounds, and sensitivity requirements below those that we need. However, it may be worthwhile studying the methods to determine more accurately whether they would apply here.

As a general guide, we have had success in the past with gas chromatographic quantitation of the analyte from the air in a headspace vial containing either blood or homogenized brain tissue; we assume that a similar approach would work with the buffer solutions as the concentration range and aqueous medium are quite similar.

11) How extensive and specific must the documentation requested for our QA/QC Protocols be to meet the burden of acceptability in response to this solicitation? Is an outline of our QA/QC policy and a copy of the manual's Table of Contents acceptable? Do you require a complete copy of our QA/QC manual?

Refer to the following guidelines:

Overall QA - see ANSI/ASQC E-4
QMP - see http://www.wpa.gov/quality/qs-docs/r2-final.pdf
QAP - see http://www/epa.gov/quality/qs-docs/r5-final.pdf

12) Please define an acceptable pre-award Quality Management Plan consistent with the specification contained in EPA/QAR-2 EPA Requirements for Quality Management Plans. Does this Quality Management Plan need to follow a specific format?

Vendors must submit an E-4 and R2 consistent Quality Management Plan with there quote. The QAPP is required as a post-award requirement that we have to examine before the measurements are actually made.